LAW OFFICES OF
FAY KAPLUN & MARCIN, LLP
INTELLECTUAL PROPERTY LAW

150 BROADWAY, SUITE 702
NEW YORK, NEW YORK 10038
PHONE: (212) 619-6000
FAX: (212) 619-0276
WWW.FKMIPLAW.COM

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FROM	:	Oleg F. Kaplun, Esq. Fay Kaplun & Marcin, LLP
DATE	:	April 2, 2008
SUBJECT	:	US Patent Appln. Serial No. 10/768,565 for *Pressure Actuated Safety Valve with High Flow Slit* Inventor(s): Weaver et al. Our Ref.: 10123/00801

NUMBER OF PAGES INCLUDING COVER : 17

MESSAGE:

Please see attached.

Attorney Docket No.: 10123/00801 (03-325)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Weaver et al.
Serial No.	:	10/768,565
Filed	:	January 29, 2004
For	:	Pressure Actuated Safety Valve with High Flow Slit
Group Art Unit	:	3763
Confirmation No.	:	6338
Examiner	:	Theodore J. Stigell

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By: Oleg F. Kaplun (Reg. No. 45,559) Date: April 2, 2008

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TRANSMITTAL

Transmitted herewith please find a Reply Brief in response to the Examiner's Answer mailed on February 26, 2008, for filing in the above-identified application. No fees are believed to be required. The Commissioner is hereby authorized to charge any additional required fees to the Deposit Account of **Fay Kaplun & Marcin, LLP No. 50-1492.** A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: April 2, 2008

By: _____
Oleg F. Kaplun, Reg. 45,559

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276

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Dated: April 2, 2008

By:
Oleg F. Kaplun, Reg. 45,559

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276

PATENT
Attorney Docket No.: 10123 - 00801

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	
Weaver et al.	
Serial No.: 10/768,565	Group Art Unit: 3763
Filed: January 29, 2004	Examiner: Theodore J. Stigell
For: PRESSURE ACTUATED SAFETY VALVE WITH HIGH FLOW SLIT	**Board of Patent Appeals and Interferences**

Mail Stop: Appeal Brief - Patents
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Arlington, VA 22313-1450

REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed on February 26, 2008 to the Appeal Brief filed on December 26, 2007, and pursuant to 37 C.F.R. § 41.41, Appellant presents this reply brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 - 21 in the Final Office Action dated July 2, 2007 as clarified in the Advisory Action dated September 18, 2007. The appealed claims are set forth in the attached Claims Appendix.

1. Status of the Claims

Claims 1 - 21 have been rejected in the Final Office Action, and are the subject of the present appeal.

2. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 1–21 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,707,357 to Mikhail et al. (hereinafter "Mikhail")

3. Argument

I. The Rejection of Claims 1 - 21 as Anticipated by Mikhail Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1–21 were rejected under 35 U.S.C. 102(b) as anticipated by Mikhail. (*See* 7/2/07 Office Action, p. 2).

Claim 1 recites a pressure actuated valve for controlling the flow of fluid through a medical device, comprising a flow control membrane "including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen".

Mikhail generally describes "a palpitatable valve that may be selectively manipulated by the patient". (*See* Mikhail, col. 6, ll. 2 - 4). The Mikhail device comprises a valve, such as valve 38 comprising a plurality of openings 76. (*See* Id. at col. 22, ll. 38-62; Fig. 5). The valve 38 is moved from a closed configuration, as shown in Figs. 3 and 4, to an open configuration, as shown in Fig. 5, by squeezing the wall 40 of the valve 38 radially inward, thereby causing a deformation thereof. (*See* Id. at col. 22, ll. 38-62; Figs. 3-5). Alternate embodiments of the Mikhail device disclose palpitatable valves with differently shaped openings 76 located therein

the valves. (*See* Id; Figs. 7,8, 21-35).

B. Mikhail does not Disclose a Pressure Actuated Valve as Recited in Claim 1

Initially, it is noted that all of the valves of Mikhail are opened only through manual actuation (i.e., squeezing the valve). (*See* Id. at col. 22, ll. 38-62; Figs. 3-5). The valve of the Mikhail is designed to give a patient control over the release of urine from the bladder by remaining sealed at all times regardless of the pressure applied thereto and permitting flow only when the patient manually opens the valve. (*See* Mikhail, col. 2, ll. 8 - 21) Any opening of the valve of the valve of the Mikhail device due to fluid pressure would therefore represent a failure of the device. (*See* Id.). It is therefore respectfully submitted that Mikhail does not describe "a *pressure actuated* valve" including a flow control membrane "including a plurality of slits extending therethrough, wherein, *when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen,*" as recited in claim 1.

In response, the Examiner has indicated that there is no limitation of a fluid pressure recited in claim 1. (*See* 2/26/08 Examiner's Answer, pp. 6 - 7). However, it is respectfully submitted that claim 1 clearly recites a "pressure actuated valve" including "a flow control membrane" including slits opening when the membrane is "acted upon by a pressure of at least a threshold magnitude." It is respectfully submitted that, as made clear by the preamble to the claim and as made further clear by the specification which describes only fluid pressures as opening the disclosed valves, the "pressure" recited in claim 1 is fluid pressure. Furthermore, as described in detail in the specification, the pressure of a "predetermined magnitude" is a fluid pressure sufficient to separate the edges of the slit in the membrane. No other type of pressure (e.g., manual pressure) is ever shown or suggested in the claim as opening the valve. Throughout

the specification, the terms pressure and flow pressure are used interchangeably and thus, it is submitted that the recitation in claim 1 of "[a] pressure actuated valve for controlling the flow of fluid through a medical device," which includes "a flow control membrane [...] including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen," clearly refers to a fluid pressure.

The Examiner further contends that there is inherently a fluid pressure at which the slits of Mikhail would open. (*See* 2/26/08 Examiner's Answer, pp. 6-7). Specifically, the Examiner has noted that the valve of Mikhail is elastic and is therefore capable of opening under a fluid pressure while maintaining structural integrity. (*Id.*). In response to the Appeal Brief filed on December 26, 2007, the Examiner has refuted the argument that opening of the valve of Mikhail under a fluid pressure would be detrimental thereto, citing specifically that this argument is conclusory and is not supported by the disclosure of Mikhail. (*Id.*). However, it is noted that Mikhail describes "a palpitatable valve that may be selectively manipulated by the patient." (*See* Mikhail, col. 6, ll. 2 - 4). That is, the valves of Mikhail are opened only through manual actuation by squeezing the valve. Mikhail does not contemplate or suggest that the palpitatable valve can be opened by fluid pressure. There is no reason whatsoever to assume that the palpitatable valve could successfully open in response to "a pressure of at least a threshold magnitude," as recited in claim 1 nor is there any reason to assume that such an opening would not represent a failure of the valve. It is further stressed that a modification to a device may only be applied where there is some teaching, suggestion, or motivation to do so. (*See* In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335, Fed. Cir. 2006.) Mikhail describes a process by which the palpitatable valve opens in response to *inward radial pressure*, which is exerted by *manual*

squeezing. (*Id.* at col. 22, lines 42 - 62). Thus, Mikhail's valve is specifically designed to open only when subjected to manual pressure. The use of fluid pressure is completely against the teachings of Mikhail, as the device is designed to prevent fluid flow despite the fluid pressure exerted by the urine. (*Id.* at col. 2, lines 8 - 21).

It is further noted that Mikhail teaches away from the use of predetermined operational pressure ranges to open a valve to flow therethrough. (*Id.*). Any opening of the valve of Mikhail due to fluid pressure would cause leakage and would represent a failure of the valve. Furthermore, by specifically reciting the undesirability of valves opening under fluid pressure in the Background of the Invention, Mikhail inherently indicates that the present invention teaches away from such a mode of operation. (*Id.*). Thus, Mikhail teaches against opening a valve in response to any kind of fluid pressure. Accordingly, it is submitted that, in addition to being undesirable, the opening of the valve of Mikhail in response to fluid pressure would also represent a failure of the device, indicating a structural or material defect, since opening to fluid pressure would never happen under normal circumstances as taught by Mikhail. It is further submitted that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (*See* In re Gordon, 733 F.2d 900, 221 USPQ 1125, Fed. Cir. 1984). Assuming it were possible to open the valve using a sufficient fluid pressure, such force either occur only in an environment other than that for which it was designed or would indicate that Mikhail's device was damaged completely defeating the entire purpose of Mikhail. Furthermore, it is respectfully submitted that a reading of the prior art which equated the fact that all structures must eventually fail under some fluid pressure with a pressure activated valve completely reads these pressure related limitations out of the claim. Of course, even steel bulkhead doors and

dams will open (i.e., fail) under some excessive fluid pressure. However, it is clear that this does not make them pressure activated valves.

For these reasons, it is respectfully submitted that Mikhail neither discloses nor suggests a *pressure actuated* valve for controlling the flow of fluid through a medical device, the valve comprising a flow control membrane "including a plurality of slits extending therethrough, wherein, *when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen*," as recited in claim 1.

Furthermore, it is noted that claim 1 recites a plurality of slits "wherein each of the slits extends between end portions thereof along a curve and *wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits*." This configuration of slits is most simply illustrated by Fig. 5 of the instant application. In contrast, none of the slit configurations shown in Mikhail shows or suggests this limitation. In response, the Examiner has interpreted the "end" of the slits of the Mikhail device to be the portion of the slit extending from the center to the end thereof. (*See* 2/28/08 Examiner's Answer, pp. 3 - 4, 7). Initially, it is noted that an end of a slit is defined as "the portion of an area or territory that lies at or by the termination and that often serves as a delimination or boundary." (*See* definition, Webster's Third New International Dictionary). It is therefore evident that the end portion can not comprise a center portion of the slit, as the center portion does not lie by the termination point thereof. Furthermore, it is respectfully submitted that one skilled in the art would not be motivated to interpret the "end portion" of a slit to extend to and constitute a center portion thereof. Rather, by this interpretation, the entire length of the slit 76 of Mikhail would be interpreted as an end when both ends are accounted for. It is further

submitted that the Examiner has improperly used hindsight in crafting the proposed modification of Fig. 33 of Mikhail to meet the limitations of claim 1. Specifically, end portions of each of the slits 76 of Mikhail do not meet the limitation of "extend[ing] between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits," as recited in claim 1. As stated above, the Examiner has sought to define the end portion of the slits 76 to extend to the center thereof to overcome this limitation. It is submitted that the argument submitted by the Examiner is impermissible and Mikhail fails to teach or suggest a plurality of slits "wherein each of the slits extends between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits," as recited in claim 1 and that claim 1 is therefore allowable over Mikhail for at least this additional reason. Because claims 2 - 9 depend from, and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 10 recites substantially similar limitations, including a flow control device for a pressure actuated valve, comprising "*a substantially planar elastic membrane* including a peripheral seating portion adapted to be secured to a housing of the pressure actuated valve and a central portion including a first curved slit extending therethrough, the elastic membrane biasing the first slit to a closed configuration in which edges of the first slit are in contact with one another to prevent flow past the membrane, wherein, *when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane moves to an open configuration in which the edges of the first slit are separated from one another so that fluid may flow past the membrane through the first slit.*" It is therefore respectfully submitted that this claim is allowable

for the same reasons stated above in regard to claim 1.

In addition, it is noted that each of the valves of Mikhail is a "dome-type" valve. (*See* Mikhail, col. 27, ll. 6 - 55; Fig. 3). Specifically, the valves of the Mikhail device are dome shaped and are not "substantially planar", as recited in claim 10. The Examiner asserts that the term "planar" means lying in a plane. (*See* 2/28/08 Examiner's Answer, pp. 7 - 8). However, the Examiner's reading which forces a domed valve into this definition is inconsistent with the common definition of the term planar, which means flat or level. This definition of planar is well-known to those skilled in the art and is even used repeatedly throughout Mikhail. For instance, Mikhail describes a mandril with a "generally flat or planar section" and deforming the valve into a "flat or planar configuration." (*See* Mikhail, col. 24, ll. 44 - 60). Accordingly, it is noted that the dome shaped valve of Mikhail is not planar, but rather, occupies a clearly non-planar dome shape with no flat surfaces at all. The Examiner further contends that the membrane 38 substantially lies in a plane. (*See* 2/26/08 Examiner's Answer, p. 8). However, it is noted that, particularly in reference to Fig. 3, the valve 38 of Mikhail comprises a multi-planar configuration, wherein different lengths of the valve occupy different planes. Thus, it is respectfully submitted that Mikhail neither discloses nor suggests "a substantially planar elastic membrane," as recited in claim 10 and that claim 10 is allowable for at least this additional reason. Because claims 11 - 16 depend from, and, therefore, include all of the limitations of claim 10, it is respectfully submitted that these claims are also allowable.

Claim 17 recites a catheter comprising "a pressure actuated valve" including a flow control membrane extending across the lumen, the membrane including a first curved slit extending therethrough, "wherein *when the membrane is subject to a pressure of at least a*

predetermined threshold magnitude, the membrane deforms to an open configuration in which edges of the first slit separate from one another to all flow through the lumen." It is respectfully submitted that claim 17 is allowable for the same reasons stated above in regard to claim 1. Because claims 18 and 19 depend from, and, therefore, include all of the limitations of claim 17, it is respectfully submitted that these claims are also allowable.

Claim 20 recites a valve including "a flow control membrane extending across a lumen of the device, the membrane including a plurality of slits extending therethrough, the slits being configured so that, *when the membrane is subjected to a flow pressure of at least a threshold magnitude*, the slits open to permit flow through the lumen". It is respectfully submitted that claim 20 is allowable for the same reasons stated above in regard to claim 1.

Claim 21 recites a catheter including "a flow control membrane extending across a lumen thereof to regulate flow through the lumen and to seal the catheter when not in use, the membrane including a first curved slit extending therethrough, the slit being configured so that... *when the membrane is subject to a flow pressure of at least the predetermined threshold magnitude*, the edges of the slit separate from one another to permit flow past the membrane." It is respectfully submitted claim 21 is allowable for at least the same reasons stated above in regard to claim 1.

9. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and indicate that claims 1 - 21 are allowable.

Respectfully submitted,

Date: April 2, 2008

By: _____
Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276

Serial No.: 10/768,565
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Attorney Docket No.: 10123 - 00801

CLAIMS APPENDIX

1. (Original) A pressure actuated valve for controlling the flow of fluid through a medical device, the valve comprising:

a housing including a lumen extending therethrough; and

a flow control membrane extending across the lumen to control the flow of fluid through the lumen, the membrane including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen and, when not acted upon by a pressure of at least the predetermined magnitude, the slits are maintained closed by a biasing force applied thereto by the membrane to prevent flow through the lumen, wherein each of the slits extends between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits.

2. (Original) The valve according to claim 1, wherein the first slit extends along a portion of a curve having a first radius of curvature and the second slit extends along a portion of a curve which is substantially a mirror image of the curve along which the first slit extends

3. (Original) The valve according to claim 2, wherein the plurality of slits includes a third slit having a third radius of curvature different from the first radius of curvature.

4. (Original) The valve according to claim 1, wherein the first and second slits are disposed substantially symmetrically about a line of symmetry of the membrane.

5. (Original) The valve according to claim 4, wherein the membrane is substantially elliptical and the line of symmetry is a major axis of the membrane.

6. (Original) The valve according to claim 4, wherein the membrane is substantially circular and the line of symmetry is a diameter of the membrane.

7. (Original) The valve according to claim 1, wherein the first and second slits are disposed substantially symmetrically about a point of symmetry of the membrane.

8. (Original) The valve according to claim 7, wherein the point of symmetry is a center of the flow control membrane.

9. (Original) The valve according to claim 1, wherein the first and second slits are spaced from one another by a distance sufficient to prevent contact between edges of the first and second slits when they are open.

10. (Original) A flow control device for a pressure actuated valve, comprising a substantially planar elastic membrane including a peripheral seating portion adapted to be secured to a housing of the pressure actuated valve and a central portion including a first curved slit extending therethrough, the elastic membrane biasing the first slit to a closed configuration in which edges of the first slit are in contact with one another to prevent flow past the membrane, wherein, when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane moves to an open configuration in which the edges of the first slit are separated from one another so that fluid may flow past the membrane through the first slit.

11. (Original) The flow control device according to claim 10, wherein the first slit extends substantially along a portion of a circle having a radius of curvature selected achieve a desired flow opening area when subject to the predetermined threshold pressure.

12. (Original) The flow control device according to claim 10, wherein the membrane further includes a second curved slit extending through the central portion, wherein the first and second slits are separated by a distance sufficient to prevent contact between the edges of the first slit and edges of the second slit when the first and second slits are in the open configuration.

13. (Original) The flow control device according to claim 10, wherein the elastic membrane is a polymeric membrane.

14. (Original) The flow control device according to claim 12 wherein the first and second slits are disposed substantially symmetrically about a line of symmetry of the membrane.

15. (Original) The flow control device according to claim 14, wherein the membrane is substantially elliptical and wherein the line of symmetry is one of a major and a minor axis of the

membrane.

16. (Original) The flow control device according to claim 14, wherein the membrane is substantially circular and wherein the line of symmetry is a diameter of the membrane.

17. (Original) A dialysis catheter comprising:

a catheter body having a distal end insertable into a blood vessel, a proximal end connectable to a dialysis machine and a lumen extending between the proximal and distal ends; and

a pressure actuated valve disposed in the lumen to regulate flow therethrough and to seal the catheter when not in use, wherein the valve includes a flow control membrane extending across the lumen, the membrane including a first curved slit extending therethrough, wherein, when the membrane is not subject to a pressure of at least a predetermined threshold magnitude, the membrane is biased into a closed configuration in which edges of the first slit abut one another to prevent flow through the lumen and, when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane deforms to an open configuration in which edges of the first slit separate from one another to all flow through the lumen.

18. (Original) The dialysis catheter according to claim 17, wherein the membrane further comprises a second curved slit, wherein the first and second slits are separated by a distance sufficient so that, when the membrane deforms to the open configuration, the edges of the first slit do not contact edges of the second slit.

19. (Original) The dialysis catheter according to claim 17, wherein the predetermined threshold magnitude corresponds to a pressure that would be induced within the lumen by connection of an operating dialysis machine to the proximal end and, wherein the predetermined threshold magnitude is substantially greater than pressure that would be induced by action of a patient's vascular system.

20. (Previously Presented) A valve for controlling flow through a medical device, the valve comprising a flow control membrane extending across a lumen of the device, the membrane

including a plurality of slits extending therethrough, the slits being configured so that, when the membrane is subjected to a flow pressure of at least a threshold magnitude, the slits open to permit flow through the lumen and, when subjected to a flow pressure of less than the threshold magnitude, the slits are maintained closed by a biasing force applied thereto by the membrane to prevent flow through the lumen, each of the slits extending between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits defines a minimum distance between the first and second slits.

21. (Previously Presented) A catheter comprising a flow control membrane extending across a lumen thereof to regulate flow through the lumen and to seal the catheter when not in use, the membrane including a first curved slit extending therethrough, the slit being configured so that, when the membrane is subject to a flow pressure of less than a predetermined threshold magnitude, edges of the slit are held in contact with one another through a bias of the membrane to prevent flow past the membrane and, when the membrane is subject to a flow pressure of at least the predetermined threshold magnitude, the edges of the slit separate from one another to permit flow past the membrane.